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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,060	02/18/2004	Bart De Corte	PRD-26 CIP	5753

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EXAMINER	
BALLS, ROBERT J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,060	DE CORTE ET AL.	
	Examiner	Art Unit	
	R. James Balls	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-90 are pending.

2. This application is a CIP of application serial No.10/641,964 filed on August 15, 2003 (abandoned), which claims benefit of provisional application No. 60/404,239 filed on August 16, 2002.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claim 6, wherein R_1 is NR_4R_6, tetrahydropyrimidinyl(R_8) or tetrahydro-1,8-naphthyridinyl(R_8) classified in classes 544, subclass 358 & 546 subclasses 122 . An election of a single disclosed species is also required.

II. Claim 5 (excluding that claimed in Claim 6) wherein R_1 is dihydro-1H-pyrrolo[2,3-b]pyridinyl(R_8), tetrahydro-1H-azepino[2,3-b]pyridinyl(R_8) or pyridinyl(R_8) classified in class 546, various subclasses depending on species election. An election of a single disclosed species is also required.

III. Claim 4 (excluding that claimed in Claim 5 and 6) wherein R_1 is heterocycle(R_8) or heteroaryl(R_8) classified in class 544-549 depending on species election. An election of a single disclosed species is also required.

IV. Claims 1-3 and 7-38 (excluding the subject matter claimed in Claims 5-6 and 39) class 546 and various subclasses depending on species election. An election of a single disclosed species is also required.

V. Claim 45, wherein R_1 is NR_4R_6, tetrahydropyrimidinyl(R_8) or tetrahydro-1,8-naphthyridinyl(R_8) classified in class 424, subclass 181.1. An election of a single disclosed species is also required.

VI. Claim 44 (excluding that claimed in Claims 77 and 45) wherein R_1 is dihydro-1H-pyrrolo[2,3-b]pyridinyl(R_8), tetrahydro-1H-azepino[2,3-b]pyridinyl(R_8) or pyridinyl(R_8) classified in class 424, subclass 181.1. An election of a single disclosed species is also required.

VII. Claim 43 (excluding that claimed in Claims 44-45 and 77) wherein R_1 is heterocycle(R_8) or heteroaryl(R_8) classified in class 424, subclass 181.1. An election of a single disclosed species is also required.

VIII. Claim 40-42 and 46-74 (excluding the subject matter claimed in Claims 43-45 and 76-77) classified in class 424, subclass 181.1. An election of a single disclosed species is also required.

IX. Claim 85 and 86-90 wherein R_1 is NR_4R_6, tetrahydropyrimidinyl(R_8) or tetrahydro-1,8-naphthyridinyl(R_8) classified in class 424 subclass 450. An election of a single disclosed species is also required.

X. Claims 84 and 86-90 (excluding that claimed in 85) wherein R_1 is heterocycle(R_8) or heteroaryl(R_8) classified in class 424 subclass 450. An election of a single disclosed species is also required.

XI. Claims 79-83 and 86-90 (excluding that claimed in 84-85) classified in class 424 subclass 450. An election of a single disclosed species is also required.

XII. Claim 78 and 86-90 drawn to therapeutic liposome compositions (excluding those claimed in Claims 79-85) classified in Class 424, Subclass 450. An election of a single disclosed species is also required.

Claims 1-3 and 7-38 link inventions I-IV; Claims 40-42 and 46-74 link inventions V-VIII; and Claims 79-83 and 86-90 link inventions IX-XI. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claims. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions **shall** be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejections are governed by 37 CFR 1.116; amendments submitted after allowances are governed by 37 CFR 1.312.

Applicants are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions I-IV, drawn to targeting ligands. Inventions V-VIII, drawn to targeting conjugates derived from the targeting ligands of Inventions I-IV. Inventions IX-XI are drawn to liposomes derived from the targeting conjugates of Claims V-VIII, which are derived from the targeting ligands of Inventions I-IV. Invention XII is drawn to all therapeutic liposomes. The restriction is between the different structures of the targeting ligands and between the targeting ligands, the targeting conjugates and the liposomes.

The targeting ligands have independent and distinct structures, which lack a substantial structural feature recognized in the art as being essential to the disclosed utility. A reference that anticipates any one of groups I-XII would not render the other groups obvious. A search for one group is not coextensive with a search of any other group and it would be a tremendous burden to search all the groups without restriction. Should applicants traverse on the ground that the compounds are not patentably

distinct, applicant should submit evidence or identify such evidence now or record showing compounds of groups I-IV are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a). Accordingly, in the instant case, there could be no patentability of all the claims over Wayne et al., CA 123:758624, Registry No. 166951-31-1.

Inventions I-IV are related to inventions V-VIII, as they are derived from the same targeting ligands. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together **or** can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, a reference that anticipates any one of groups I-IV would not render groups V-VI obvious. Should applicants traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now or record showing compounds of groups I-IV are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a). Accordingly, in the instant case, there could be no patentability of all the claims over Wayne et al., CA 123:758624, Registry No. 166951-31-1.

Inventions I-IV are related to inventions IX-XI, as they are derived from the same targeting ligands. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together **or** can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, a reference that anticipates any one of groups I-IV would not render groups IX-XI obvious. Should applicants traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now or record showing compounds of groups I-IV are obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a). Accordingly, in the instant case, there could be no patentability of all the claims over Wayne et al., CA 123:758624, Registry No. 166951-31-1.

Inventions V-VIII and IX-XI are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product, and the species are patentably distinct (MPEP § 806.05(j)). In the instant case, the intermediate product is deemed to be useful for a purpose other than making the final product. Iversen et al., (U.S. Patent No. 6,784,291), discloses a targeting agent conjugated with polyalkyleneoxy (PEG), which is useful to inhibit normal expression of a protein. That is, the intermediate has a therapeutic use on its own without being made

into the final product (i.e. a liposome). See column 4, lines 21-23. The intermediate and final products are deemed patentably distinct because there is nothing on the record to show them to be obvious variants. Furthermore, a search of both inventions is not coextensive and would impose a serious burden on the office.

Inventions XII is not related to any of inventions I-XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, there is no requirement that the liposome contain any targeting ligand or conjugate disclosed elsewhere in the specification. A reference that anticipates group XII would not render groups I-XI obvious. Should applicants traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now or record showing that invention XII is an obvious variant of any of inventions I-XI or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in an obviousness rejection under 35 USC §103(a). Accordingly, in the instant case, there could be no patentability of all the claims over Allen et al., (U.S. Patent No. 6,316,024), which discloses and claims the same therapeutic liposome as applicants' claim 78. See U.S. Patent No. 6,316,024, Claim 1.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though th erequirement be traversed. 37 CFR 1.17(i).

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls
September 6, 2006

Celia Chang
Primary Examiner
Art Unit 1625